

**REMARKS**

The above-identified application has been considered in view of the Final Office Action that was mailed on August 14, 2008. Claims 1-35 are currently pending, of which, Applicant has amended independent claims 1, 19, 28, 31, and 33 herein. Applicant respectfully submits that the amendments to independent claims 1, 19, 28, 31, and 33 add no new matter and are fully supported by the specification. In view of these amendments and the following remarks and arguments, Applicant respectfully submits that the pending claims are allowable over the references of record, and accordingly, respectfully requests reconsideration and allowance of the above-identified application.

Applicant wishes to thank the Examiner for the courtesies extended to Applicant's Representative during a telephone interview conducted on October 2, 2008.

Claims 1-5, 7-9, and 12-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,215,521 to Cochran *et al.* (hereinafter "Cochran") in view of U.S. Patent No. 5,480,404 to Kammerer *et al.* (hereinafter "Kammerer") and further in view of U.S. Patent No. 6,387,102 to Pagedas (hereinafter "Pagedas"). Applicant respectfully submits, however, that the combination of Cochran, Kammerer, and Pagedas fails to suggest each and every element recited in claims 1-5, 7-9, and 12-32 as presented herein.

Applicant respectfully maintains that the pending claims are allowable as previously presented in an Amendment dated March 3, 2008 that was submitted in connection with the

above-identified application. However, in the interests of advancing prosecution, Applicants have amended independent claims 1, 19, 28, 31, and 33 herein to more clearly distinguish the subject matter recited in the pending claims from the references of record.

As amended, independent claims 1 and 31 each recite a tissue removal device that includes, *inter alia*, a bag that is repositionable between unfolded and folded positions, whereby “a distal portion of the tissue removal device defines a transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.”

As amended, independent claim 19 recites a method of collapsing a bag of a tissue removal device that includes the steps of, *inter alia*, providing a tissue removal device with a bag that is repositionable between unfolded and folded positions, and folding the bag such that at least one transverse fold is formed, “whereby a distal portion of the tissue removal device defines a transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.”

As amended, independent claim 28 recites a tissue removal device that includes, *inter alia*, a bag that is repositionable between unfolded and folded positions, the bag being folded over onto itself so as to form at least one transverse fold “such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a relatively

smaller transverse cross-sectional dimension, when the bag is in the folded position, as compared to a distal portion of the tissue removal device including a like bag, in a folded position, that is devoid of said at least one transverse fold.

Cochran relates to an organ retrieval apparatus including an entrapment envelope 22 that is inserted into an inflated body cavity through an elongate sheath 20. (*See* col. 8, lines 12-18; *see* FIG. 4).

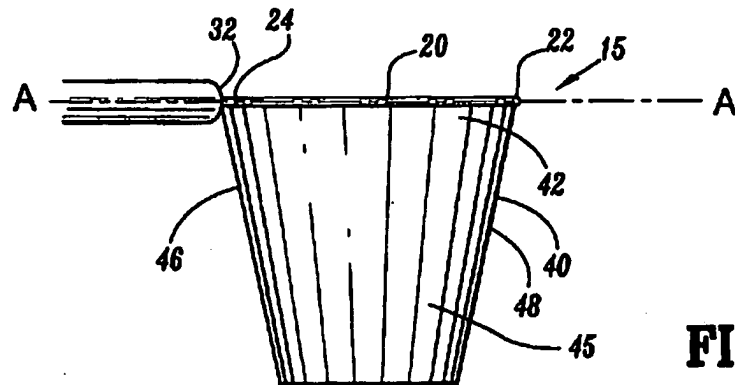
Kammerer relates to a tissue retrieval instrument including an elongated support tube 52 having a finger grip 54 mounted to a proximal end thereof. (*See* col. 6, lines 6-8; *see* FIG. 1). At a distal end of the support tube 52, a collapsible pouch 64 is supported by a flexible belt 66 that is slidably received by the support tube 52. (*See* col. 6, lines 12-15).

Pagedas relates to “a reusable surgical device and methods for accessing and retrieving tissue or other mass from a body cavity.” (Col. 1, lines 18-20; *see* FIG. 1). In one embodiment, the surgical device 11 includes an elongated wand 12 with a front end 14 and a back end 16, an elongated rod 18 having a handle portion 24, and a removable bag 50. (*See* col. 4, line 63 – col. 5, line 12.)

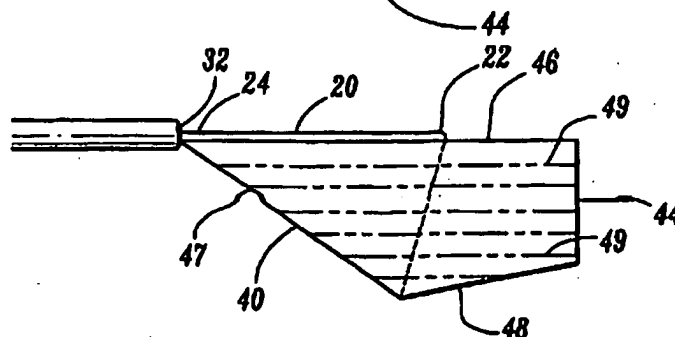
In the Office Action, the entrapment envelope 22 described in the Cochran apparatus was characterized as the “bag” recited in claims 1-5, 7-9, and 12-32. The Examiner acknowledged that the entrapment envelope 22 fails to include the recited “at least one transverse fold,” but argued that the entrapment envelope 22 is capable of folding transversely. (*See* Final Office Action, page 3). Alternatively, the Examiner relied upon Kammerer for the disclosure of a “bag”

including a "transverse fold," pointing specifically to FIGS. 3 and 4 of Kammerer. (See Final Office Action, pages 3-4). Additionally, the Examiner acknowledged that the combination of Cochran and Kammerer does not disclose a bag that is folded onto itself when collapsed into a folded position, but relied upon Pagedas for disclosure of this concept, arguing that the bag 50 described in Pagedas is folded as recited in the claims during use. (See Final Office Action, page 4).

According to the present disclosure, the bag 40 recited in the pending claims is repositionable between unfolded and folded positions, e.g., in preparation for packaging, as seen below in the transition between FIGS. 3 and 4. (See page 13, lines 15-18). The present disclosure states that folding the bag 40 in this manner "has been found to produce a low profile folded bag, such that smaller diameter tubes can be used." (See page 13, lines 18-20).

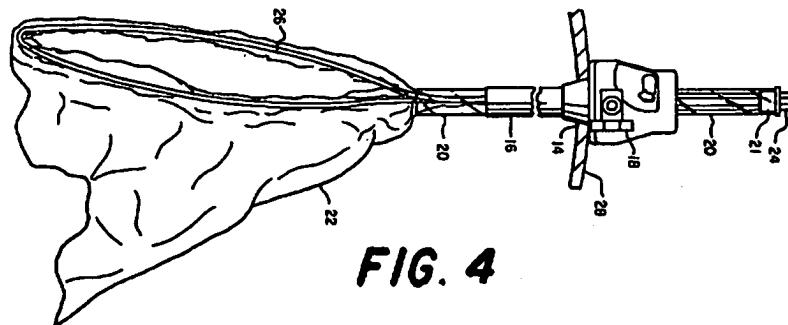


**FIG. 3**



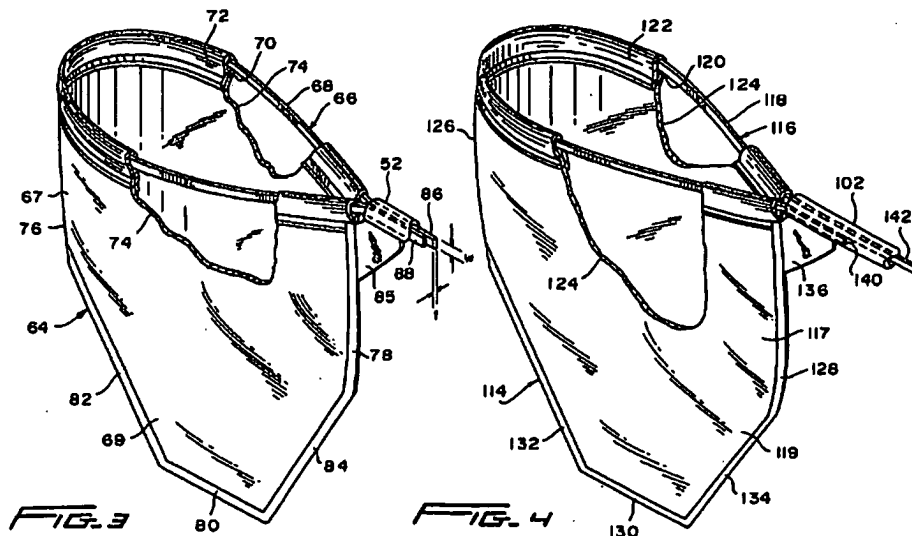
**FIG. 4**

While the entrapment envelope 22 described in Cochran may be characterized as including an uneven or furrowed outer surface, contrary to the “bag” recited in the claims, the entrapment envelope 22 does not include the recited “transverse fold.” (See FIG. 4 below). As such, in preparing the Cochran apparatus for insertion into a patient, the entrapment envelope 22 is withdrawn into the sheath 20. The entrapment envelope 22 is never folded. Rather, the entrapment is simply collapsed as it is drawn proximally through an opening at a distal end of the sheath 20.



**FIG. 4**

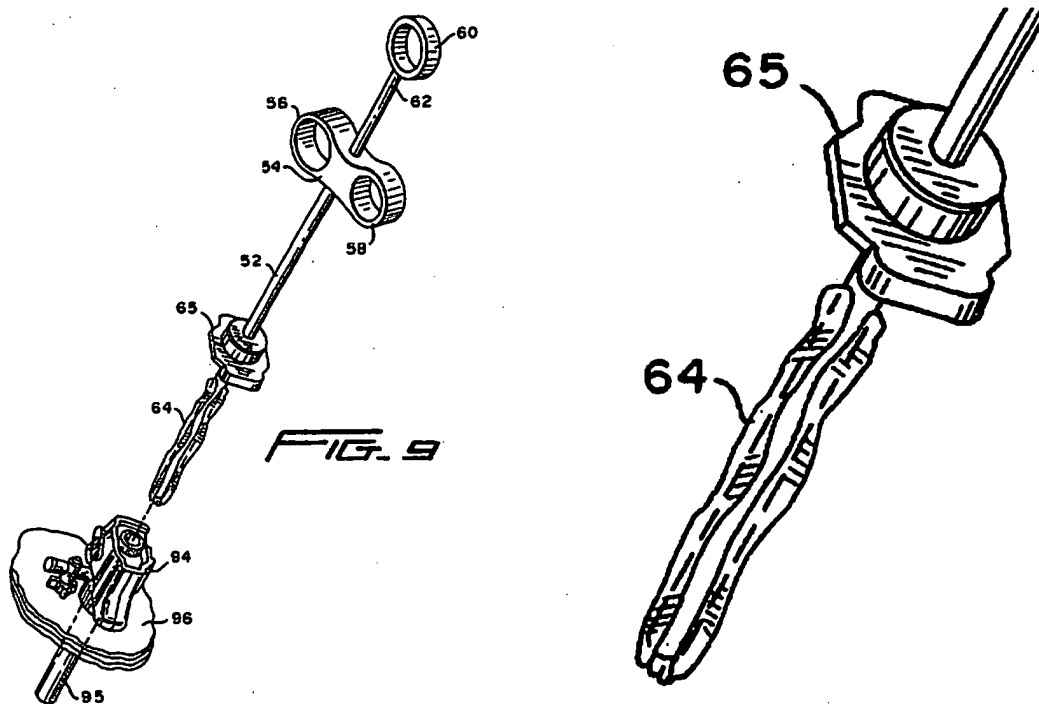
Similarly, while the embodiment of the Kammerer pouch 64 relied upon by the Examiner includes “a pair of tapered edges 82 and 84,” (col. 6, line 49; see FIGS. 3-4), the pouch 64 does not include the recited “transverse fold.”



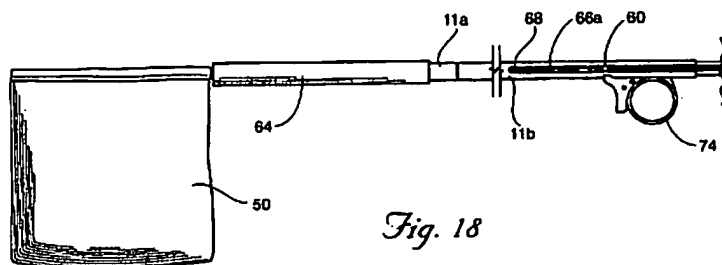
**FIG. 3**

**FIG. 4**

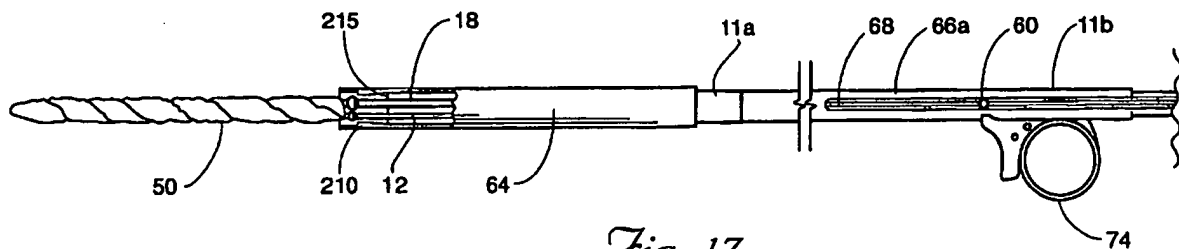
As such, in preparing the Kammerer instrument for insertion into a patient, the pouch 64 is never folded. Rather, "the mouth of the pouch 64 is closed by pulling the finer ring 60 in the proximal direction to contract the belt loop 68 into the support tube 52," (col. 8, lines 53-55), such that the pouch 64 becomes wrinkled and deformed about the distal end of the instrument, as seen below in FIG. 9 and the corresponding enlargement.



With reference to FIG. 18 below, the Pagedas device includes a bag 50 that is conspicuously absent any "transverse fold."



In preparing the Pagedas instrument for insertion into a patient, the bag 50 is never folded. Rather, Pagedas discloses that the bag 50 is wrapped around the distal portion of the instrument to achieve the rolled configuration seen below in FIG. 17 and facilitate insertion of the instrument through a laparoscopic port. (See col. 7, lines 60-63).



*Fig. 17*

Applicant respectfully submits that failing to include the recited “transverse fold” and preparing the Cochran, Kammerer, and Pagedas instruments as described above results in an insertion configuration wherein the distal portion of each instrument defines a cross-sectional transverse dimension that is unnecessarily relatively large, as compared to a distal portion of the instrument including a like bag having the transverse fold of the present application.

Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits that neither Cochran, Kammerer, Pagedas, nor any proper combination thereof, discloses or suggests a tissue removal device including a bag that is repositionable between unfolded and folded positions, whereby “a distal portion of the tissue removal device defines a transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like

bag, in a folded position, devoid of said at least one transverse fold,” as recited in amended independent claims 1 and 31. Likewise, Applicant respectfully submits that the references of record, taken either alone or in any proper combination, fail to disclose or suggest a tissue removal device including a bag that is repositionable between unfolded and folded positions, the bag being folded over onto itself so as to form at least one transverse fold “such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a relatively smaller transverse cross-sectional dimension, when the bag is in the folded position, as compared to a distal portion of the tissue removal device including a like bag, in a folded position, that is devoid of said at least one transverse fold,” as recited in amended independent claim 28.

As the references of record fail to disclose or suggest a bag including a “transverse fold,” considered both individually and in any proper combination, *a priori*, Applicant respectfully submits that the references of record also fail to disclose or suggest a method of collapsing a bag of a tissue removal device that includes the steps of, *inter alia*, “folding the bag such that at least one transverse fold is formed, “whereby a distal portion of the tissue removal device defines a transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold,” as recited in amended independent claim 19. To the contrary, as previously discussed, Cochran describes withdrawing and collapsing the entrapment envelope 22 into the sheath 20, Kammerer



describes contracting the belt loop 68 into the support tube 52 to wrinkle and deform the pouch 64 about the distal end of the instrument, and Pagedas describes wrapping the bag 50 around the distal portion of the instrument.

For at least these reasons, *inter alia*, Applicant respectfully submits that neither Cochran, Kammerer, Pagedas, nor any proper combination thereof, discloses or suggests each and every element recited in amended independent claims 1, 19, 28, and 31, and therefore, that amended independent claims 1, 19, 28, and 31 are allowable over Cochran in view of Kammerer and Pagedas under 35 U.S.C. §103(a). As claims 2-5, 7-9, 12-18, 20-27, 29, 30, and 32 depend either directly or indirectly from amended independent claims 1, 19, 28, and 31 and include each element recited therein, for at least the reasons that amended independent claims 1, 19, 28, and 31 are allowable over Cochran in view of Kammerer and Pagedas under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that claims 2-5, 7-9, 12-18, 20-27, 29, 30, and 32 are also allowable over Cochran in view of Kammerer and Pagedas under 35 U.S.C. §103(a).

Claims 1, 4, and 6 were rejected under 35 U.S.C. §103(a) as being unpatentable over Pagedas in view of U.S. Patent No. 5,899,694 to Summer (hereinafter "Summer"). Applicant respectfully submits, however, that the combination of Pagedas and Summer fails to suggest each and every element recited in claims 1, 4, and 6 as presented herein.

In the Final Office Action, the Examiner acknowledged that Pagedas fails to disclose a sheath "fabricated from a flexible heat-shrinking polymer," as recited in claim 6, and relied on Summer for disclosure of this concept.

As previously discussed, Pagedas fails to disclose or suggest each and every element recited in amended independent claim 1. Assuming, *arguendo*, that the Examiner's purported characterization of Summer is accurate, including the sheath purportedly disclosed therein would fail to cure the aforescribed deficiencies in Pagedas.

Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits the combination of Pagedas and Summer fails to suggest each and every element recited in amended independent claim 1, and therefore, that amended independent claim 1 is allowable over Pagedas in view of Summer under 35 U.S.C. §103(a). As claims 4 and 6 depend either directly or indirectly from amended independent claim 1 and include each element recited therein, for at least the reasons that amended independent claim 1 is allowable over Pagedas in view of Summer under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that claims 4 and 6 are also allowable over Pagedas in view of Summer under 35 U.S.C. §103(a).

Claims 10 and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Kammerer and Pagedas, and further in view of U.S. Patent No. 6,402,722 to Snow *et al.* (hereinafter "Snow"). Applicant respectfully submits, however, that the combination of Cochran, Kammerer, Pagedas, and Snow fails to suggest each and every element recited in claims 10 and 11 as presented herein.

In the Final Office Action, the Examiner acknowledged that the combination of Cochran, Kammerer, and Pagedas fails to disclose "a cord operatively connected to the tear line for facilitating the tearing of the sheath along the tear line," as recited in claim 10, and relied on

Snow for disclosure of this concept.

As previously discussed, the combination of Cochran, Kammerer, and Pagedas fails to disclose, or even suggest, each and every element recited in amended independent claim 1. Assuming, *arguendo*, that the Examiner's purported characterization of Snow is accurate, including the cord purportedly disclosed therein would fail to cure the aforescribed deficiencies in the combination of Cochran, Kammerer, and Pagedas.

Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits the combination of Cochran, Kammerer, Pagedas, and Snow fails to suggest each and every element recited in amended independent claim 1, and therefore, that amended independent claim 1 is allowable over Cochran in view of Kammerer, Pagedas, and Snow under 35 U.S.C. §103(a). As claims 10 and 11 depend either directly or indirectly from amended independent claim 1 and include each element recited therein, for at least the reasons that amended independent claim 1 is allowable over Cochran in view of Kammerer, Pagedas, and Snow under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that claims 10 and 11 are also allowable over Cochran in view of Kammerer, Pagedas, and Snow under 35 U.S.C. §103(a).

Claims 33-35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Pagedas. Applicant respectfully submits, however, that Pagedas fails to disclose or suggest each and every element recited in claims 33-35 as presented herein.

As discussed above, Pagedas fails to disclose or suggest a bag including a "transverse fold." *A priori*, Applicant respectfully submits that Pagedas also fails to disclose or suggest a

method of collapsing a bag of a tissue removal device that includes the steps of, *inter alia*, “folding the bag such that at least one transverse fold is formed, “whereby a distal portion of the tissue removal device defines a transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold,” as recited in amended independent claim 33. To the contrary, as previously described, Pagedas discloses wrapping the bag 50 around the distal portion of the instrument.

Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits that Pagedas fails to disclose or suggest each and every element recited in amended independent claim 33, and therefore, that amended independent claim 33 is allowable over Pagedas under 35 U.S.C. §103(a). As claims 34 and 35 depend either directly or indirectly from amended independent claim 33 and include each element recited therein, for at least the reasons that amended independent claim 33 is allowable over Pagedas under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that claims 34 and 35 are also allowable over Pagedas under 35 U.S.C. §103(a).

In the RESPONSE TO ARGUMENTS section of the Final Office Action, the Examiner again acknowledged that both Cochran and Kammerer fail to disclose a collapsible bag that includes the “transverse fold” recited in the pending claims. However, the Examiner argued that “it would have been obvious to try various folds to collapse and maneuver the retrieving

member.” (See Final Office Action, pages 8-9). In the alternative, the Examiner again relied upon Pagedas for disclosing a bag including the recited “transverse fold.” (See Final Office Action, page 9).

Applicant respectfully submits that neither Cochran nor Kammerer identify any deficiency in the manner of preparing the entrapment envelope 22 or the pouch 64 (i.e., withdrawing and collapsing the entrapment envelope 22 into the sheath 20, and contracting the belt loop 68 into the support tube 52 to wrinkle and deform the pouch 64), respectively, prior to inserting the disclosed instruments into a patient. Moreover, neither Cochran nor Kammerer suggest a desirability of producing “a low profile folded bag, such that smaller diameter tubes can be used” that are identified in the present specification and addressed by the instruments and methods recited in the pending claims. Accordingly, contrary to the Examiner’s statement, Applicant respectfully submits that it would not have been obvious to “collapse” or “maneuver” the entrapment envelope 22 and pouch 64 discussed in Cochran and Kammerer, respectively.

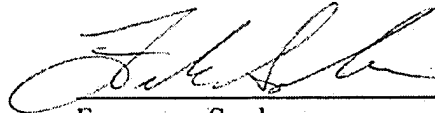
Additionally, Applicant reiterates that Pagedas discloses a bag devoid of the “transverse fold” recited in the pending claims, and that the bag is wrapped around the distal portion of the instrument to facilitate insertion.

In view of the foregoing, Applicant respectfully submits that pending claims 1-35 are allowable over the references of record, and respectfully requests reconsideration and allowance of the above-identified application.

If the Examiner should have any questions concerning this Preliminary Amendment, or feel that an interview would be helpful in resolving any outstanding matters, the Examiner is sincerely invited to contact Applicants' undersigned attorney at her convenience.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefor.

Respectfully submitted,



Francesco Sardone  
Reg. No. 47,918  
Attorney for Applicants(s)

***Carter, DeLuca, Farrell & Schmidt, LLP***  
445 Broad Hollow Road, Suite 225  
Melville, New York 11747  
Phone: (631) 501-5700  
Fax: (631) 501-3526

**Send correspondence to:**  
Chief Patent Counsel  
Covidien  
60 Middletown Avenue  
North Haven, CT 06473